



Health, Nutrition and Related Claims: Enabling Provisions in New Zealand Law

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The proposals in this paper are for consultation purposes and do not necessarily represent agreed Government policy.

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1 Introduction

This public discussion document is intended to provide information and seek submissions on proposed regulatory measures to give legal effect in New Zealand to Standard 1.2.7 Health, Nutrition and Related Claims of the Australia New Zealand Food Standards Code (the Code).

The Code is comprised of standards for the regulation of food sold in Australia and New Zealand and is administered by Food Standards Australia New Zealand (FSANZ), a trans-Tasman regulatory body established under the provisions of the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System (the Food Treaty – 1995).

This document does not seek comment on the proposed Standard itself. FSANZ has undertaken two rounds of consultation in development of the proposed Standard and is currently undertaking a third. This final round of consultation provides opportunity for interested parties to make submissions on the preliminary final assessment report. Submissions to the FSANZ consultation process close on 16 May 2007. Further information about the FSANZ consultation process and access to documents in relation to the proposal for Standard 1.2.7 (P293) are available on the FSANZ website at www.foodstandards.govt.nz.

2 Consultation

Submissions on the proposals to give legal effect to health claims standards in the Code are invited from interested parties.

2.1 Requirements for submissions

The submission should include:

- the title of this discussion document
- name and title of submitter
- organisation's name (if applicable)
- submitter's address and contact details (phone, fax, e-mail if available)
- the number(s) of the section(s) commented on, beside each comment
- the extent of internal consultation undertaken in preparing the submission.

2.2 Address for submissions

Please send your submission to:

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2.3 Closing date for submissions

The closing date for submissions is 14 May 2007.

2.4 Official Information Act

The Official Information Act 1982 (OIA) states that information is to be made available unless there are grounds for withholding it. Grounds for withholding information are in the OIA. Submitters may wish to indicate grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. NZFSA will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

2.5 Process after submissions

After the closing date, submissions received will be taken into account when providing advice to the Minister for Food Safety and Minister of Health on the proposals. A recommendation will then be made by the Minister to the Governor-General who may agree to amend legislation to give effect to resulting proposals.

3 Background

3.1 Introduction

In New Zealand, health, nutrition and content claims relating to food products are regulated under the Australia New Zealand Food Standards Code (the Code). The Code has been developed to regulate all food sold in Australia and New Zealand and is administered by Food Standards Australia New Zealand (FSANZ), a trans-Tasman regulatory body established under the provisions of the Food Treaty. As a signatory to this treaty, New Zealand is obliged “to take such legislative or other steps as are necessary to adopt or incorporate, by reference and without amendments” any food standards recommended to and adopted by the Australia New Zealand Food Regulation Ministerial Council (the Ministerial Council), the political body that oversees the work of FSANZ. This obligation is realised in New Zealand statutory law under section 11B(b) of the Food Act 1981 which gives effect to the Food Treaty.

3.2 The current situation

At present, nutrition claims are allowed under the Code. These are detailed in Standard 1.2.8 Nutrition Information, and include claims in relation to:

- polyunsaturated or monounsaturated fatty acid content of foods;
- omega fatty acid content of foods
- low joule claims in relation to food
- lactose claims in relation to food
- the gluten content of food, and
- the salt, sodium or potassium content of food.

Vitamin and mineral content claims, including claims that a food is “a good source” of a vitamin or mineral are permitted under Standard 1.3.2 Vitamins and Minerals.

Health claims, however, are prohibited in the Code by Transitional Standard 1.1A.2 with one exception: the claim that the maternal consumption of folate reduces the risk of neural tube defects in developing foetuses.

In New Zealand, health claims related to food also fall under the jurisdiction of the Medicines Act 1981, which prohibits the application of therapeutic claims to a category of product called Related Products defined under the Act to include any “food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose.”

Therapeutic purpose is defined in the Medicines Act as:

- treating or preventing disease, or
- diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition, or
- Altering the shape, structure, size, or weight of the human body, or
- Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.

The folate health claim enabled by Transitional Standard 1.1A.2 in the Code is considered a therapeutic claim under the Medicines Act. It was therefore necessary in 1998, when the Transitional Standard was introduced into the Code, to grant an exemption for the folate health claim under the Medicines Act so as to give the claim legal effect in New Zealand and thereby fulfil New Zealand’s obligations under the Food Treaty.

This exemption, the Medicines (Related Products (Exempted Foods)) Regulations 1998, had a built-in “sunset” or expiry clause and was subsequently repealed and replaced in 1999 and 2000, to facilitate the extension of the folate health claim pilot project and in 2002 and 2003 to allow time for the determination of future policy. As with the earlier exemptions, the exemption of the folate health claim under the Medicines (Related Products (Exempted Foods)) Regulations 2003 has a built-in “sunset clause.” The exemption will expire on 13 August 2007.

With the anticipated introduction of the Health Claims Standard, it is now necessary that an exemption to the Related Products provisions of the Medicines Act be made indefinite. It is therefore necessary to publicly consult on the objectives and options associated with making the exemption indefinite.

3.3 Scope of the discussion document

It must be emphasised that the scope of this discussion document is limited to the regulatory mechanism best suited to give legal effect to Standard 1.2.7 in New Zealand. Public consultation on the proposal for the Standard itself is being carried out by FSANZ in a separate process. The preliminary final assessment report on the proposed Standard (P293) was released for a six week consultation closing on 16 May 2007.

Further Information about the Standard and access to the preliminary final assessment report is available at:

<http://www.foodstandards.govt.nz/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>.

3.4 Standard 1.2.7 Health, Nutrition and Related Claims

The future policy for health claims in New Zealand and Australia was decided on 12 December 2003 when the Ministerial Council endorsed a Health, Nutrition and Related Claims Policy Guideline that included folate and a range of other health claims. FSANZ is currently developing Standard 1.2.7 Health, Nutrition and Related Claims (the Health Claims Standard) through a process of commissioned research, research reviews and public consultation.

The basic design of the proposal for the Health Claims Standard is the categorisation of health claims as either high level, for which specific permissions will be available in the Code, or general level, for which manufacturers will be responsible for substantiating claims and holding substantiation information. FSANZ is also developing qualifying criteria to ensure that food products carrying health claims do not exceed set limits for their food type of components such as saturated fats, sugars or sodium.

Several diet-disease relationships have been scientifically substantiated through reviews commissioned by FSANZ. High-level health claims based on the following diet-disease relationships will be pre-approved in the Health Claims Standard:

- the relationship between the high dietary intake of calcium, vitamin D status, and the reduced risk of the frail elderly, especially women, developing osteoporosis
- the relationship between the high dietary intake of calcium and enhanced bone mineral density, particularly in women
- the relationship between reduction in the dietary intake of sodium and reduction in blood-pressure

- a relationship between reduction in the dietary intake of saturated fatty acids and a reduction in LDL-cholesterol levels
- a relationship between reduction in the dietary intake of trans-fatty acids and saturated fatty acids and a reduction in LDL-cholesterol levels, and
- a relationship between increased intakes of folic acid in the peri-conceptual period and the reduced risk of the development of neural tube defects in fetuses.

As with high-level claims, general-level claims will need to be substantiated in an appropriate science-based framework, however, evidence of this substantiation will be held by the manufacturers or suppliers of the food product. FSANZ has developed material to assist in determining whether manufacturer or supplier evidence is sufficient to substantiate a general level claim.

3.4.1 Impacts of the Health Claims Standard on industry

For industry, it is a commercial decision as to whether a health claim is applied to a product. In making such a choice, any costs associated with the labelling and marketing of that product will be borne by industry as a marketing investment and potentially passed on to the consumer only in the instance when the consumer deigns the health benefit gained by consuming the product to outweigh the financial cost of purchasing it.

3.4.2 Impacts of the Health Claims Standard on consumers

In order to ascertain the impact of health claims applied to food products on consumers, FSANZ has carried out detailed research into consumer responses to claims. These findings and other detailed research have informed the design of the Health Claims Standard. The results of the FSANZ commissioned research returned a considerable variability in responses but there were a number of common findings across the study that underpinned participants' responses and behaviours.

Further detail of research commissioned by FSANZ is available on the FSANZ website at:

<http://www.foodstandards.govt.nz/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>

It is anticipated that the specific criteria for high level claims will ensure that consumers are given accurate information about products with verifiable health benefits. The Health Claims Standard will also be coordinated with the other labelling standards in the Code to ensure the provision of detailed and accurate information to consumers.

3.4.3 Compliance

The Health Claims Standard will provide a clear framework for compliance. It will give confidence to manufacturers and retailers in designing labels and marketing devices to meet the requirements of New Zealand law and will also provide consumers with assurance that the information provided on food labels is not misleading.

4 The problem

In order for products carrying the folate health claim to remain on the market in New Zealand after 13 August 2007, it is necessary that the exemption from their classification as Related Products enabled by the Medicines (Related Products (Exempted Foods)) Regulations 2003 be extended. Transitional Standard 1.1A.2 does not have a specific expiry date but will expire two years after the introduction of the Health Claims Standard. It is expected that the Health Claims Standard will be gazetted in November or December 2007.

In order for New Zealand to meet its obligations under the Food Treaty with Australia and our statutory requirements under section 11B(b) of the Food Act 1981, the Transitional Standard 1.1A.2 and the Health Claims Standard need to be given legal effect in New Zealand Law.

While New Zealand may “opt-out” or vary from a standard (covered by Annex C of the Food Treaty), this action is constrained to situations where exceptional health, safety, third country, environmental or cultural factors exist. The Food Treaty also stipulates that any New Zealand variation shall not create a barrier to trade unless exceptional health, safety and environmental concerns exist. In the cases of the folate health claim and the Health Claims Standard, “opting out” or variance from these standards is not an option as exceptional circumstances do not exist.

The Medicines Act 1981 prohibits the application of therapeutic claims to any Related Product including foods. The high level claims and some general-level claims in the proposal for the Health Claims Standard are considered therapeutic claims under the Medicines Act. It is therefore necessary to take legislative steps to exempt foods that carry such health claims approved under the Code from prohibition.

There is currently a Bill before Parliament proposing the repeal of the Medicines Act 1981 with provisions to enable the establishment of a trans-Tasman agency to regulate therapeutic products under a joint regulatory scheme. The Therapeutic Products and Medicines Bill, in its draft form, does not require an exemption for health claims of the form proposed for the Health Claims Standard because the category of Related Product does not exist in the Bill. It is unlikely however, that the new regulatory scheme will be in place before the current exemption mechanism expires on 13 August 2007.

5 Objectives

In considering measures to give legal effect to the Transitional Standard 1.1A.2 and the proposed Health Claims Standard, NZFSA has four principal objectives.

1. The first objective is to allow for the continued sale of products carrying the folate health claim beyond the expiry of the Medicines (Related Products (Exempted Foods)) Regulations 2003 on 13 August 2007. If measures to continue the exemption for the folate health claim are not taken, packaging will have to be relabelled to remove the claim, thus imposing unnecessary costs on industry. The folate health claim is also part of a wider public health initiative encouraging at-risk groups to increase their consumption of folate. Removing the ability for the health claim to be applied to qualifying products will hamper this initiative.
2. The second objective is to meet New Zealand's statutory obligation under the Food Act 1981 and our obligation under the Food Treaty to give legal effect to standards in the Code. This obligation is framed by the wider Trans Tasman Mutual Recognition Arrangement (TTRMA) under which the Food Treaty sits.
3. The third objective is to ensure the integrity and adequacy of information provided to consumers by manufacturers and retailers in relation to food products and to provide consequences should that information be misleading.
4. The fourth objective is to provide a clear framework and administrative process through which products can be developed bearing health claims and in which industry can be confident they are meeting the requirements of New Zealand law.

6 Options considered

The New Zealand Food Safety Authority (NZFSA) is the government agency with responsibility for food regulation and the coordination of all food policy in New Zealand. NZFSA is also the advisory body to New Zealand's representative on the Ministerial Council. As such, NZFSA is undertaking the regulatory change to the Medicines Act necessary to give legal effect to the Transitional Standard 1.1A.2 and the Health Claims Standard.

NZFSA has considered the option of taking no action; of leaving the Medicines Act Regulations as originally drafted. This was considered unacceptable as it does not meet any of the four objectives detailed in section 5.

NZFSA has consequently identified three possible options for giving legal effect to the folate health claim and the Health Claims Standard. The three options are:

- a. Amend section 94(1) of the Medicines Act to exclude from the definition of Related Product any food (a) in respect of which therapeutic claims are otherwise regulated under the Code, and (b) which complies with standards in the Code.
- b. Replace the current Medicines (Related Products (Exempted Food)) Regulations 2003 with a wider ranging exemption under Section 94(1)(b) and 105 of the Medicines Act. This would exempt claims defined as health, nutrition or related claims under certain parts of the Code (ie. those high-level claims listed in the Health Claims Standard or those that qualify as general-level claims). Section 94(1)(b) and 105 of the Act provide for regulations to be made exempting certain substances or articles from classification as Related Products for the purposes of the Act. This, for example, may classify foods carrying "health claims that comply with the Code" as exempt from the provisions of the Act.
- c. Rely on the new Therapeutic Products and Medicines Bill currently before Parliament to be enacted before 13 August 2007. The Therapeutic Products and Medicines Bill will replace the Medicines Act 1981 and obviate the need for legislative measures to give legal effect to health claims standards under the Code.

7 Options analysis

7.1 Option (a): amend the Medicines Act 1981

This option meets the objectives described in section 5. It also provides for the implementation of any applicable future health claims standards developed in the Code.

The principal issue with this option is that it would involve the amendment of a primary piece of legislation and would thus require passage through the New Zealand Parliament. This process is likely to take a considerable amount of time. It would be unlikely that an amendment would be in place by 13 August 2007 when the current exemption for the folate health claim expires.

7.2 Option (b): replace the current Medicines (Related Products (Exempted Food)) Regulations

Section 105 of the Medicines Act allows for the promulgation of regulations under the Act. A regulation can be drafted under this section and section 94(1)(b) of the Act exempting food products carrying health claims approved under the Health Claims Standard in the Code. This is the same kind of mechanism currently used to exempt the folate health claim from the provisions of the Act that prohibit therapeutic claims. Thus regulations can be made to exempt certain substances or articles from classification as Related Product. This, for example, may classify foods carrying "health claims that comply with the Code" as exempt from the provisions of the Act.

This option meets all of the objectives described in section 5 above and provides an effective regulatory solution to the implementation of Standard 1.2.7. It will require the approval of the Minister for Food Safety, the Minister of Health and Cabinet and can be gazetted before the expiry of the existing exemption on 13 August 2007.

7.3 Option (c): rely on the new Therapeutic Products and Medicines Bill

The new Therapeutic Products and Medicines Bill currently before Parliament does not include the category of Related Products and thus would not conflict with the health claims standards in the Code.

Although relying on the Bill to obviate the need for an exemption has the potential to be an effective solution and meet the objectives described in section 5, this would create a very tight timeframe between the current timeline for implementation of the Therapeutics Products and Medicines Bill and the expiry of the current exemption mechanism for the folate health claim. Such a tight timeframe would not allow for any unplanned delay of the implementation of the Therapeutics Products and Medicines Bill.

8 The proposal

After a preliminary analysis of the options summarised in the section above, NZFSA proposes to replace the Medicines (Related Products (Exempted Foods)) Regulations 2003 with new regulations that exempt food products carrying claims regulated under the Code from classification as Related Products under the Medicine Act 1981 (option (b), paragraph 7.2).

The Therapeutic Products and Medicines Bill, as it is drafted, does not retain the category of Related Products from the Medicines Act. Therefore when this Bill is passed into law the exemption regulation will no longer be necessary and will be repealed with the Medicines Act.

8.1 Impacts of the proposed regulations

The impact of legislative measures to give legal effect to the health claims standard in the Code is minor. As enabling legislation the proposed regulations would impose no cost on the economy.

9 Implementation and review

9.1 Implementation

The timeline for implementation of policy proposals arising out of this consultation process is limited by the expiry of the Medicines (Related Products (Exempted Foods)) Regulations 2003 on 13 August 2007. It is expected that the legislative measures to exempt health claims from prohibition under the Medicines Act will be gazetted before this date, in July 2007. Meeting this date will ensure that products carrying the folate health claim can legally remain on the New Zealand market.

The regulatory measures proposed in this discussion document will enable health claims only if the permissions for the claims are available in the Code. If the proposals in this discussion document come into effect before 13 August 2007, health claims (excluding the folate claim) will still be prohibited under Transitional Standard 1.1A.2. The introduction of proposed Health Claims Standard, which will permit health claims under the Code, is dependent upon the FSANZ consultation and approval process. New Zealand is involved in this process through representation on the Ministerial Council and through the three New Zealand members on the Board of FSANZ. New Zealanders are also able to make comment on any FSANZ proposals under consultation. The implementation of the Health Claims Standard, and thus the ultimate enabling of health claims, remains the responsibility of FSANZ.

The Transitional Standard 1.1A.2 will expire two years after the introduction of the Health Claims Standard. The Health Claims Standard is anticipated for gazettal in November or December 2007. Upon gazettal of the new standard, health claims will be permitted under either the Health Claims Standard or the Transitional Standard 1.1A.2 during the two year transition.

9.2 Review and evaluation of the Health Claims Standard

One of the policy guidelines for the development of the Health Claims Standard is that it and the administrative processes it establishes will be reviewed within two years of its implementation. The FSANZ review process assesses the effectiveness and appropriateness of food regulatory measures by assessing the long term impact for stakeholders and provides evidence to inform future decisions on food regulation.

FSANZ's Evaluation Strategy 2004 – 2008 establishes a consultative approach, eliciting input from the FSANZ Advisory Group on Evaluation, which has representatives from key stakeholders in Australia and New Zealand, such as the food industry, consumer groups, health professionals and enforcement officers. The Australian Government Departments of Health and Ageing (DoHA), Agriculture, Fisheries and Forestry (DAFF) and Employment and Work Relations (DEWR) each contribute an advisor to the FSANZ Data and Evaluation Steering Committee, which oversees the evaluation. The Evaluation Strategy is available on the FSANZ website at:

<http://www.foodstandards.govt.nz/newsroom/publications/evaluationstrategy202463.cfm>.

Recommendations arising from the evaluation are forwarded to the FSANZ Board for information and final reports on the outcomes of research are made available to the public on the FSANZ website. Recommendations which may influence broad policy issues will also be forwarded for information to the Food Regulation Standing Committee (FRSC) and/or the Implementation Sub-Committee (ISC), recognising these committees' interests in the development of a broad policy framework for setting food standards.

9.3 Enforcement

The proposed Health Claims Standard provides clear guidelines in making claims against food products. To ensure that these guidelines are complied with, FSANZ proposes to establish a “watchdog” group to monitor compliance. Enforcement of compliance is the responsibility of individual jurisdictions. In New Zealand, enforcement procedures and penalties are already included in both the Food Act 1981 and the Medicines Act 1981.

10 Additional information for submitters

Comments from all those with an interest in any aspect of the proposals presented in this document are invited. Clear and concise comments will assist in ensuring that the significance of your comments is understood.

The following points may be of assistance in preparing comments:

- some questions are included below to assist you in providing comment on this paper
- wherever possible, comments should be specific to a particular section of the document
- comments should be to the point and, where possible, give reasons and data in support
- the use of examples to illustrate particular points is encouraged
- a number of copies may be made of your comments so please ensure that your comments are clear, preferably made in black ink or typewritten.

10.1 Requirements for submissions

Submitters are asked to include the following information in submissions:

- the title of this discussion document
- name and title of submitter
- organisation's name (if applicable)
- extent of internal consultation within organisation undertaken in preparing submission
- submitter's address and contact details (phone, fax, e-mail if available)
- the number(s) of the section(s) commented on, beside each comment.

10.2 Address

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10.3 Closing date for submissions

The closing date for submissions is 14 May 2007.

10.4 Submission format

This format is included to assist interested parties in formulating submissions:

Your view

Name:

Address:

1. The consultation process
2. The need for regulatory change
3. Options:
 - a. Amend the Medicines Act 1981
 - b. Repeal and replace the Medicines (Related Products (Exempted Food)) Regulations 2003
 - c. Rely on the new Therapeutic Products Bill currently before Parliament to be implemented before 13 August 2007.
4. Proposal – NZFSA proposes option 2 (paragraph 7.2)
5. Impact on industry
6. Impact on consumers
7. Any other comments